UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC

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PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO EXCLUDE THE EXPERT TESTIMONY OF MARK J. EISENBERG M.D.

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EXHIBIT 1

Deposition of:

Mark Eisenberg , M.D., M.P.H.

August 17, 2016

In the Matter of:

Clare-Austin vs. C.R. Bard

Tiffany Alley, A Veritext Company
1075 Peachtree St. NE , Suite 3625
Atlanta, GA, 30309
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epidemiologist.

A. Yes, I am.

Q. Define for us what a clinical epidemiologist is.

A. Well, I have a masters of public health degree from Harvard where I studied biostatistics and epidemiology as well as other topics. So I spent half my time doing clinical cardiology, including interventional cardiology, and I spent half my time doing research. And the research that I do is clinical epidemiology research, so that involves clinical trials, systematic reviews, meta analyses, cohort studies as well as a variety of other methodologies that are within the rubric of clinical epidemiology.

Q. Have you ever been the lead investigator of a clinical trial?

A. I have.

Q. On how many occasions?

A. I believe five clinical trials.

Q. Generally what did those clinical trials involve?

A. I did two clinical trials with patients who had percutaneous coronary interventions -- among patients who had

and, as I understand, that was also statistically significant, I believe, although I am not as -- I didn't have complete access to that internal testing data, or perhaps it was in the documents I had but I didn't see it all.

BY MR. NORTH:

Q. You have mentioned a number of sort of sources of information: Dr. Betensky's analysis, the consultant's analysis. Did you make any independent assessment as to whether the complication data showed a statistically significant safety signal?

A. Can you repeat that again?

Q. Okay. You tell us the data showed a safety signal. Did you independently yourself calculate whether that signal was statistically significant?

A. So you know, I do a lot of this research, this type of research in my regular practice where I do systematic reviews and meta analyses. So I am quite experienced in looking at the totality of evidence from multiple sources to do that determination. I did not do any analyses myself. I think that, you know, I went over in detail the Betensky analyses and I am

questions?

A. Yes, I do.

Q. And do you recall at one point you provided an answer about whether reviewing -- whether reviewing an internal document required particular expertise?

MR. NORTH: Objection, leading.

THE WITNESS: Yes, I recall that.

BY MR. ROTMAN:

Q. What -- can you explain your answer on that issue?

MR. NORTH: Objection.

THE WITNESS: Yes. I am glad you asked, because I think I was not as clear as I could have been, which was, I think -- I think that when you read internal company documents for a device company there are certain things that a lay person can read and understand such as crisis management, alarmingly high rate. So there are things that do not require particular expertise to understand. But let's face it, this whole area is dealing with things that a lay person could not understand, that you need to be a medical expert of some sort in order to even know what an IVC filter is, to know what tilt, to know

what perforation, embolization, fracture. All of those issues, you need to be an expert in order to read the documents. In order to know about relative risk and statistically significant differences you need to have some epidemiologic biostatistical background. To know about -- and I only went through a very small portion of the internal documents, but in order to, you know, to look at the totality of the internal documents and see how the company dealt with the FDA, for example, you would need somebody who was an expert, you know, with FDA industry relations, which I am not. So I think that while there are, you know, an isolated communication, some of them a lay person might be able to read and certainly would potentially be alarmed at. Other internal documents you clearly need different types of expertise. For example, you know, migration testing, you need somebody who knows about in vitro testing which, you know, I don't portray myself as an expert in that area. So I think you need different types of experts in order to read and interpret different parts of, you know, internal company documents.

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE BARD IVC FILTERS
PRODUCTS LIABILITY
LITIGATION,

NO.
MD-15-02641-PHX-DGC

VIDEOTAPED DEPOSITION OF MARK J. EISENBERG, MD
ON THURSDAY, JULY 6, 2017
IN MONTREAL, QUEBEC, CANADA.

VIDEOGRAPHER: DAVID OXILIA

COURT REPORTER: C.L. KLEIN

A. Well, I don't think I have formally taught a course on pharmacovigilance. Although I don't hold myself out as an expert in pharmacovigilance, many of the research studies I have done have involved, you know, safety and certainly efficacy studies of different devices and drugs, so I have a fair amount of knowledge on pharmacovigilance. I don't think I have formally taught a course on that topic.

Q. Let me break that down a little bit, and you let me know if I get this wrong; okay? Some of the research you have done in the past touches on issues of product safety; right?

A. Yes.

Q. You don't hold yourself out as an expert in pharmacovigilance; right?

A. Again, I would say it's one of the areas that I have some knowledge in, but do I hold myself out as an expert in that area? Probably not.

Q. You are not an expert in corporate ethics; right?

A. No.

Q. You are not an expert in responsible corporate conduct; right?

say the same thing, I may have paraphrased.
BY MR. BUSMAN:
Q. Now, obviously you didn't purport to have reviewed every single document produced in this litigation; right?
A. No, that's correct.
Q. Your understanding is that was millions of pages of documents; right?
A. Yes.
Q. How did you go about -- strike that. Who chose the corporate documents that you, yourself, reviewed?
A. Well, I was provided with a Drop Box of a huge number of corporate documents from which I could, you know, pick and choose. My attention was drawn to certain corporate documents by the Lawyers as well. I would say also, in my reading through this case, I have also gone back to see other documents that perhaps were referred to in other expert reports.
Q. The universe of corporate documents that you were provided -- strike that. The universe of corporate documents you had access to were provided by the Plaintiffs' Attorneys; right?

A. Yes.
Q. Within that universe of documents you were specifically directed to certain documents that the Plaintiffs' Attorneys wanted your opinions on; right?
A. In many instances, yes.
Q. Did you, yourself, draft this expert report?
A. Yes, I did.
Q. You wrote every word of it?
A. Yes.
Q. Now, obviously your focus in this case was on the specific documents that support your theory of the case; right?
A. Repeat that.
Q. We established that there were potentially millions of pages produced in this litigation; right?
A. Yes.
Q. Your focus was on documents that support your specific theory of the case; right?
MR. ROTMAN: Objection.
THE WITNESS: No, I wouldn't say that. I think that I -- I looked at most of the documents, not all of the documents, that the

Lawyers directed me to. I also looked at a variety of other documents that were available to me. I looked at even other documents that were referred to in other reports. So I was mostly looking at the documents to see -- I would say what the time sequence -- what happened, and when it happened, and what was known and when was it known.

BY MR. BUSMAN:

Q. Thank you. Your focus in the expert report that you prepared was on the documents that support your theory of the case. Would that be fair?

MR. ROTMAN: Objection.

THE WITNESS: Again, I don't know if this speaks to your question. If I found documents that were not in support of my thoughts or -- about this case -- how can I say, they were clearly discrepant from other documents, I probably would have included them. I didn't encounter any of those documents.

BY MR. BUSMAN:

Q. Would I be correct in saying that, in your review of documents for your work in this case, you didn't see any documents that were

discrepant with your theory of the case?
A. Again, I think that --
MR. ROTMAN: Objection.
THE WITNESS: I wouldn't say that I looked at these documents with a theory of -- "theory of the case". I looked at the documents to see when -- when were the different design modifications made to the various filters, what kinds of analyses were being done by Bard, what were the results of those analyses. I looked at emails between officers at Bard and with their consultant. I looked at things like HHE's. So I wouldn't -- I wouldn't say that I looked at this with a particular theory of the case going in. I was just looking at the documents to see what the time sequence of what happened, and what types of analyses were done, and when they were done, what the results were, what did they do with those results.
BY MR. BUSMAN:
Q. Did you review every document -- strike that. Did you review every internal corporate document that was in the Drop Box that you had access to?
A. No, I did not.

Roberts and Calva are?

A. That's correct.

Q. In paragraph 23 you state that your expert opinions are focused primarily on the reasonable expectation that physicians have of medical device companies like C.R. Bard. You say that in part; right?

A. Yes.

Q. Are you, in this litigation, attempting to give an opinion on what other doctors would think and expect or are you speaking for yourself?

A. I think that I am pretty reflective of the average physician in terms of what they would expect from a device company.

Q. What body, organization or group has given you the authority to speak for other physicians in this case?

A. I think you could say that about any one individual physician, that perhaps they don't have authority from an organization to speak on behalf of other physicians, but we -- you know, we talk to each other constantly. We have conferences constantly. We read the same medical literature where there is papers, and there is

letters to the editor, and there is editorials and opinion pieces. We go to major meetings. So there is a community of physicians that, you know, largely know what other physicians think about things.

Q. Is there a single body, group, organization of any kind that has deputized or authorized you to speak for any other physician in this case?

A. No, I wouldn't say that.

Q. You understand that reasonable physicians can have different opinions on any one of a number of topics; right?

A. Yes, I understand that. There is some extreme positions on either side of many medical issues, but I think the bulk of physicians are largely in agreement on most things. But certainly there is a range of opinions about various medical issues.

Q. What, if anything, have you done in any formal way to determine what percentage of physicians would agree with your opinions in this case?

A. Well, I certainly haven't spoken to any physicians specifically about IVC filters,

are knowledgeable about the risks and benefits associated with the procedure and the device. That's dependent on having that information available to them.

Q. Let me hand you what we will mark as Exhibit 8.

Exhibit 8 was marked for identification.

BY MR. BUSMAN:

Q. Do you recognize this as the document identified in paragraph 24?

A. Yes.

Q. Take a look at the very top, if you will, right under the heading: "Chapter Two, Opinions on Consent, Communications and Decision Making". I will read it into the record.

"The opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law."

Did I read that correctly?

A. Yes.

Q. Do you agree with that statement?

A. Well, I certainly agree that it's offered as ethics guidance. I -- you know, I understand the simple meaning of the rest of the sentence. I can't say as to whether that has actually -- has been established as standards of clinical practice or rules of law.

Q. I think that's fair. Let me try to break that down into the two components. You understand and appreciate that the document that we have marked as Exhibit 8 referenced in paragraph 24 provides ethical guidance?

A. Yes.

Q. As to whether or not it establishes a standard of any kind or rule of law, you can't answer one way or the other; right?

A. I think that most physicians would understand that the recommendations by the American Medical Association are pretty strong ethics guidelines, and most physicians would attempt to follow them. I don't know if that answers your question.

Q. I think so. Let me try to rephrase it. You think that most physicians would understand that Exhibit 8 constitutes pretty strong ethical guidelines that should be

retrievable filters compared to the Simon Nitinol filter.

Q. You speak often in your report about higher complication rates; right?

A. Yes.

Q. What do you understand the word "rate" to mean?

A. No, you know, rates have -- in epidemiology rates have very specific meanings, to use perhaps some lay terms differently, but frequency occurrence would be the lay understanding of rates.

Q. Now, of course you are a clinical epidemiologist; right?

A. Yes.

Q. You have got significant training in epidemiology; right?

A. Yes, I would say I have a fair amount of training in epidemiology. I have certainly done more than 20 years of research using epidemiologic tools, epidemiology type of research.

Q. You understand that word choices in epidemiology are significant? Words have very specific meanings in the world of epidemiology?

Q. What specific expertise are you bringing to bear with respect to your opinions in paragraph 33?

MR. ROTMAN: Objection.

THE WITNESS: I am sorry. Could you repeat that question?

BY MR. BUSMAN:

Q. What specific expertise are you bringing to bear with respect to your opinions in paragraph 33?

MR. ROTMAN: Objection.

THE WITNESS: My expertise comes from two points of view. One is as a clinician who puts in permanent and temporary devices into patients, who obtains informed consent from patients, who takes care of patients that have permanent devices in them, and on the other hand is my experience as a clinical epidemiologist who does studies looking at the safety and efficacy of different drugs and devices.

BY MR. BUSMAN:

Q. You don't reference any medical literature in paragraph 33, do you?

A. No, I do not.

Q. The evidence that led you to the

MR. ROTMAN: Objection.

THE WITNESS: So for the first part I cannot point you to a particular document that says that if Bard finds out that its product is not functioning as well as they thought, they had a legal responsibility to provide this material to physicians. But as a physician, as someone who has decades of experience with medical devices and certainly decades of research experience looking into patient safety, I think that it's clear that it was misleading for a company to say that their retrievable devices function as well as or better than the predicate device. But I cannot point you to a particular document.

BY MR. BUSMAN:

Q. Okay. Keep that in your mind, because I am going to ask the question again and I am going to ask you to focus on the question that I ask.

A. Okay.

Q. You can't point to any binding law, rule, regulation, standard or document of any kind that you believe Bard violated in connection with the conduct outlined in paragraph 33; true?

Q. And according to my notes, you were asked a question in connection with paragraph 33 about whether the meaning or the import of the Bard corporate documents would be apparent to jurors. Do you recall that question?

A. Yes, I do.

Q. So can you elaborate on how it would be or what you meant by -- in your answer to that question?

MR. BUSMAN: Objection to the form.

BY MR. ROTMAN:

Q. Can you elaborate to what extent the import and the meaning of the corporate documents would be apparent to jurors?

A. I really need to clarify that, and I think I was probably not clear this morning. I think that jurors did clearly understand this data that's presented in the Bard internal documents, but it really needs to be interpreted and presented to them by an expert. There is many, many terms that are used in the corporate documents that would not be readily intelligible to a juror who is not familiar with inferior vena cava filters, who is not familiar with the MAUDE database, who is not familiar with in vitro

testing, who is not familiar with statistics. And many, many different areas are dealt with in the corporate documents. I think a juror would understand if it was interpreted and put in context by an expert, and I am talking about what's the history, what's the background, what's the temporal nature of what went on, what were the exact design changes to the IVC filter, what does the medical literature mean, what does -- what is a cohort study, what is a clinical trial, what is a retrospective study. So these are all terms and concepts that people can readily understand if it is presented to them by an expert, but it's not readily available -- readily understandable by a lay person without getting into context. For example, a four or five-fold increased risk with Recovery filter versus SNF is reported by Dr. Lehmann. What does that mean to a layman? Not much without some background and interpretation by an expert to provide that with the background.

Q. You were asked some questions this morning, a fair number of questions about areas in which you held yourself out to be an expert. Do you recall that you were asked questions on

those topics?

A. Yes, I do.

Q. So for example, you were asked if you hold yourself out to be an expert on IVC filter implantation. Do you recall questions like that?

A. Yes, I do.

Q. Do you hold yourself out to be an expert in clinical epidemiology?

A. I do.

Q. And what is clinical epidemiology?

A. So --

Q. As relates to the -- you know, to help you answer the question in a focused way, as relates to the kinds of issues that you addressed in this case.

A. So clinical epidemiology is very directly related to the kinds of issues that were looked at in this case. You have to contrast clinical epidemiology with traditional epidemiology. Traditional epidemiology is much more so about risk factors like what's the relationship between smoking and cancer, alcohol and development of cirrhosis. Clinical epidemiology is using epidemiologic principles to

look at much more clinical issues, very much like looking at inferior vena cava filters is a very clinical issue. In order to look at the evidence base for whether these filters are efficacious or not, whether they are safe or not, how do they compare to alternatives, other filters, predicate filters, you need these all sorts of epidemiologic principles. But when we use them in a very clinical context we call that clinical epidemiology, so knowledge about clinical trials, cohort studies, registries, case control studies, case series, case reports, statistics, biostatistics, limitations of studies like bias and confounding, ideas like using databases like the MAUDE database, what they can be used for and what they can't be used for, statistics that are used when looking at, for example, in vitro testing are used in statistics. Dr. Lehmann was using statistics. These are all things I have used on a daily basis, and used for decades going back to my training with a Masters of public health degree from Harvard and even before that.

Q. You testified a number of times in response to questions asked to you during the day about how certain things involving your --

that a procedure or a device or a drug is safe and efficacious, and my primary goal is patient safety. So that's what this is about.

BY MR. ROTMAN:

Q. So you were asked questions several times by Mr. Busman throughout the day about whether you could identify any binding regulation or any binding legal standard that supported your opinion about what Bard should have done regarding studies or disclosures. Do you recall that?

A. Yes, I do.

Q. And was it your purpose to -- in giving, setting forth these opinions, was it your purpose to base those opinions on what were the regulatory binding requirements?

MR. BUSMAN: Objection to the form.

THE WITNESS: No, that was not my purpose. My purpose really with this report and the research I have done into this area was really to look at what was and is necessary for patient safety with respect to IVC filters. Do we have data to say that they are safe and effective? Yes or no and, if not, what types of studies, what size studies, how should they be

vigilant about drugs or devices in terms of their safety. So it's not enough just to put these drugs and devices out there. We have to actually track them and see if there are safety issues and, if there are, we need to quantify them. And the reason we do that is because we want to make sure that everything we do is safe for the patient and actually improves either their quality of life or length of life. And as we discussed earlier today, when a physician obtains informed consent from a patient it's critically important that they have the safety information. They cannot get informed consent from a patient unless they actually have the correct safety information to present to the patient. And the patient makes their own decision the same way that it's not just the physician but the patient needs to have that safety information. It's not enough just for the physician to have it. They have to be able to present that. So if the data is not there, then it needs to be generated, or produced, or provided or disclosed.

Q. You were asked a question, a series of questions this morning and your response pertained to a period in which your medical

EXHIBIT 3

THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE BARD FILTERS	)	
	)	
PRODUCTS LIABILITY	)	No. MD-15-02641-PHX-DGC
	)	
LITIGATION	)	

- Do Not Disclose -

Subject to Further Confidentiality Review

The video-recorded deposition of LEN DeCANT, taken before Pauline M. Vargo, an Illinois Certified Shorthand Reporter, C.S.R. No. 84-1573, at the Marriott Suites O'Hare, Rosemont II Conference Room, 6155 North River Road, Rosemont, Illinois, on May 24, 2016, at 9:04 a.m.

GOLKOW TECHNOLOGIES, INC.

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information to doctors that the Recovery filter, which had been on the market for all of six weeks in full release, had failed and ended up in the heart of a patient, whereas the Simon Nitinol filter, which had been in production and distribution for 25 years had never killed a patient?

A. I'm saying we might -- I'm saying we wouldn't necessarily do that, no.

Q. Do you agree with me that the company has an obligation to disclose to the doctors who are using its medical devices all information relating to its products that those doctors would reasonably need to know in order to make determinations regarding whether to use the product?

A. Yes.

Q. And it's your position that if Bard had ultimately decided that there was not root cause despite the fact that the filter had failed and ended up in the heart, it would not have to disclose that?

A. I'm saying I don't -- yes, I guess I am saying that.

EXHIBIT 4
Redacted in Part
(Filed Under Seal)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

- - -

In Re: Bard IVC Filters Products Liability Litigation	:	No. MD-15-02641-PHX-DGC

- - -

June 2, 2016

- - -

Do Not Disclose - Subject to Further Confidentiality Review

- - -

Videotape deposition of JOHN A. DeFORD, Ph.D., taken pursuant to notice, was held at the Hilton Short Hills, 41 John F. Kennedy Parkway, Short Hills, New Jersey, beginning at 9:11 a.m., on the above date, before Kimberly A. Cahill, a Federally Approved Registered Merit Reporter and Notary Public.

- - -

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A. No.

[redacted]

A. No. You shouldn't downplay the risks. You should share as much information as you can that's appropriate, that's been scientifically validated or vetted or evaluated.

Q. And when you say share that, you should share that with the doctors that are implanting it; correct?

A. The FDA, the doctors that are implanting it. Yeah, I don't disagree with that.

Q. My question is, you should share whatever information you have about the risks of the product about which you're aware with the doctors who are implanting it; is that correct?

A. I don't disagree with the basic premise, although that's a fairly

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

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IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	No. MD-15-02641-PHX-DGC

- - -

OCTOBER 11, 2016

- - -

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

Videotaped deposition of CHRISTOPHER D. GANSER, held at HILTON SHORT HILLS, 41 John F. Kennedy Parkway, Short Hills, New Jersey, commencing at 9:32 a.m., before Margaret M. Reihl, a Registered Professional Reporter, Certified Realtime Reporter, and Notary Public.

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experience with the Recovery filter.

Don't you agree with me?

A. Once we make that determination.

Q. Okay. I agree. And you and I agree on that?

A. I do agree.

MS. DALY: Object to the form.

BY MR. LOPEZ:

Q. Once there's statistically significant evidence of that, you ought to tell doctors about it, right?

A. Once there's sufficient information that could substantiate the need to tell the doctors to help mitigate further risk.

Q. For example, statistically significant evidence of increased reporting risks of fatalities that are consistent with the company's bench testing, they ought to tell them that there is an increased risk, potential increased risk of death from migrations, right?

A. If the data is relevant and significant.

Q. I just gave you the data. There's statistically significant evidence of increased fatalities with the Recovery filter against its

EXHIBIT 6

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION) No. MD-15-02641-PHX-DGC

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF CHRISTINE L. BRAUER, Ph.D.

WASHINGTON, D.C.

WEDNESDAY, AUGUST 2, 2017

9:07 A.M.

Reported by: Leslie A. Todd

BY MR. LOPEZ:

Q Well, it --

A It's not possible for me to do, sir.

Q Isn't that the most important thing that we should be talking about in this case is what are doctors' and patients' expectations of the safety profile and the risk-benefit profile of the Recovery, G2 and all the other Bard filters, right?

MR. ROGERS: Object to the form.

THE WITNESS: I agree that it's important for a medical device manufacturer to understand healthcare professionals' expectations for performance of a product.

BY MR. LOPEZ:

Q So we know early in the -- the history of the Recovery filter, based on everything we've talked about and what you've reviewed, that the Recovery filter proved to be not as safe as the Simon Nitinol filter when -- when implanted in patients, true?

MR. ROGERS: Object to the form.

THE WITNESS: I think you're stating things in absolute black and white terms. And I

EXHIBIT 7

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

JUNE 1, 2006

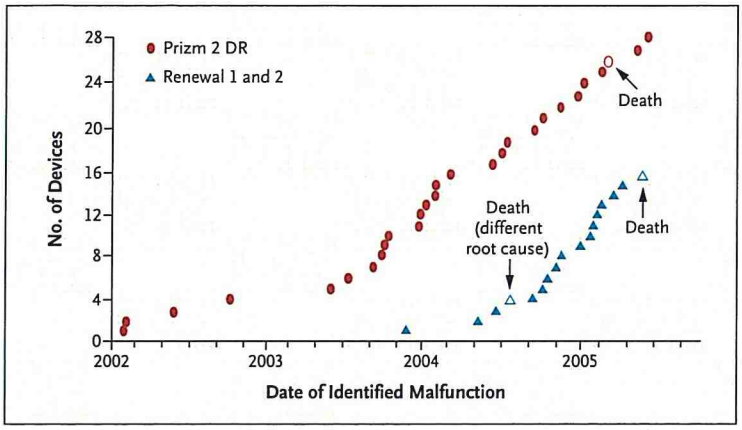
Life-Threatening Malfunction of Implantable Cardiac Devices

Robert J. Myerburg, M.D., David W. Feigal, Jr., M.D., M.P.H., and Bruce D. Lindsay, M.D.

During the summer of 2005, in the wake of widespread criticism of its failure to communicate the potentially fatal malfunctions of its implantable defibrillators,[1,2] Guidant Corporation created an independent panel, of which we were members. The purpose of the panel was to conduct an unbiased examination of these incidents, including the methods used to identify the malfunctions and evaluate products in the postmarketing phase and the policies regarding communication within the corporation and with physicians and patients. The panel was also asked to recommend corrective actions. Concurrently, the Heart Rhythm Society — which represents physicians who implant cardiac devices — established a task force to examine assessments of device performance and develop policy recommendations and guidelines.[3] Since the report by the independent panel had implications for the device industry in general, Guidant made it available to the public.[4]

Three points quickly emerged as guidelines for the panel's deliberations. First, manufactured products can never be entirely free of design or manufacturing flaws, but when the consequence of a malfunction is a potentially fatal event, tolerance and surveillance strategies should aim to achieve a risk of malfunction that is as close to zero as possible. Second, physicians must know about the performance features of any device they recommend for a patient, so that they can carry out their ethical obligation of obtaining informed consent. This information must be in a form that is understandable and clinically useful. And third, patients have a right to obtain product information so that they can make informed decisions about risks and benefits and can understand what expectations are reasonable.

The panel recognized that, as compared with the clinical benefit of implantable cardiac devices, the rate of serious malfunctions is very low. We also concluded, however, that if a malfunction is life-threatening, even a low risk of its occurrence takes on importance beyond its numbers. Although it is intuitively clear that any manufactured product will have a measurable failure rate, until recently, industry had not provided information to physicians about potentially serious malfunctions when the failure rates fell within the overall performance predic-



Defects Leading to Potential Failure in Two Types of Guidant Implantable Defibrillators.

The numbers of implantable defibrillators identified between 2002 and mid-2005 as having defects that predisposed them to short-circuiting (arcing), with an attendant risk of failure to deliver therapy when needed, are shown. The Prizm 2 DR was a conventional implantable defibrillator, and Renewal 1 and 2 were implantable defibrillators with biventricular pacing capability. Open symbols represent malfunctions that were associated with the death of a patient; one of these malfunctions was due to a random manufacturing defect rather than to the identified defect that resulted in short-circuiting ("different root cause"). Adapted from Myerburg et al.[4]

tions.[4] In most cases, these malfunctions were simply folded into overall statistics that also included less critical malfunctions and the expected depletion of batteries over time — a practice that made serious but infrequent malfunctions invisible to physicians and patients.

Although there is no industry-wide performance standard for malfunction rates in the cardiac-device industry, all companies are required by the Food and Drug Administration (FDA) to evaluate device malfunctions systematically in the post-marketing phase, to identify those that are clinically significant, to correct defects, and to act to prevent failures in performance. These internal processes necessarily center on engineering skills and methods. But the consequences of device malfunctions are more than an issue for engineering: they have clinical implications for patients that may include a risk of fatal events. Thus, engineering performance standards are insufficient benchmarks without evaluation by experts of the possible effects on individual patients. The independent panel concluded that the lack of adequate clinical expertise, combined with undue reliance on arbitrary statistical criteria, led to decisions that had potentially and manifestly serious consequences. The graph shows the number of implantable defibrillators that were identified as having defects that predisposed them to short-circuiting (arcing) between 2002 and 2005.

As the number of defibrillators with life-threatening malfunctions continued to grow, the overall reliability of the products remained within the predicted rates. Therefore, in keeping with the company's standard practices at the time, the engineering group at Guidant decided, without any input from physicians, that it was unnecessary to inform physician-customers about these events.[4] In addition, implantations of the potentially defective defibrillators continued for a time, and physicians, hospitals, and patients were not informed that the devices had flaws that could result in the inability to deliver therapy when necessary. It seems clear that the industry needs physicians with defined responsibilities focused on patient safety to provide recommendations to corporate leaders.

Post-marketing surveillance continues to be a challenge for the FDA and industry. Clinical trials rarely identify significant signals of very uncommon adverse events, and only a small proportion of later events are ever reported. One potential solution to this limitation of tracking, at least for cardiac devices, lies in the National Cardiovascular Data Registry mandated by the Centers for Medicare and Medicaid services for implantable cardioverter–defibrillators, which could be expanded and adapted to other databases. Moreover, the number of malfunctions that occur at the time of deaths that are assumed to be from natural causes remains unknown, because most devices are not returned to manufacturers for evaluation after patients die.

The FDA recently announced plans to address post-marketing surveillance more actively, including having electrophysiology experts from its Circulatory System Devices Panel review the post-marketing performance of implantable devices. The Heart Rhythm Society's task force also suggested that the FDA establish post-marketing advisory committees to recommend actions that should be taken when malfunctions are identified in defibrillators or pacemakers.[5] These steps could help the FDA address many issues, in-

cluding the lack of standard definitions and classifications of malfunctions that makes evaluating reports from different manufacturers problematic. It is uncertain whether the FDA could appreciably enhance the effectiveness of its post-marketing surveillance program without expanding both its authority and its budget. But if patient safety is a priority, the federal government should appropriate the funds required to make this effort feasible, without adversely influencing the FDA's other areas of responsibility.

In the meantime, companies must reevaluate their approach to patient safety in the context of communication. A critical question is when and how information about product performance should be communicated to physicians and patients. Although the issues — both ethical and practical — are complex, one conclusion is clear: transparency in matters that affect patient safety should be embraced as a primary corporate obligation.

In the past, this industry has not had a good record of open communication, but transparency does benefit companies that want to be viewed as trusted partners in the health care enterprise. As the panel noted, transparency may be passive, with information made available to those who seek it; active, with information targeted to specific groups of stakeholders; or forced, with a third party bringing forth information that elicits further disclosure by a company, as a defensive move. From the perspective of physicians' and patients' expectations, corporate responsibility, and public perception, we believe that proactive communication policies, centering on the proper use of active and passive transparency, should be the norm. Insofar as such communication is hindered by perceived business conflicts, the solution may lie in new regulatory definitions that distinguish informational actions from those that indicate the removal of a device. Changing language can be difficult, since much of it is embedded in statutory requirements.

The panel also recommended that Guidant establish an independent review group to provide unbiased analysis of information on product performance and advice on decisions about external communications. Voluntary, independent review at the level suggested is a notion both foreign and frightening to most corporations, whose perceived need is to protect business interests. But corporate culture fosters a loyalty to corporate goals that may create unintended bias and distorted perceptions about product performance and patient safety. Independent review groups could assist corporations by generating unbiased advice that was responsive to society's view of the best business practices and clinical priorities.

Historically, corporations have — by themselves — set the expectations for device reliability and the communication of product malfunctions, seeking little input from patients, physicians, or professional organizations. This practice developed in the early years of the industry, when the combination of small numbers of device recipients and low malfunction rates made it difficult to detect problems. With the explosive growth of the industry in recent years, previously unrecognizable signals have become increasingly visible. Clearly, strategies for evaluating and communicating device malfunctions must be adjusted accordingly. Our conclusion is that industry should work collaboratively with physicians, professional societies, patient representatives, and regulatory agencies to establish reasonable standards and guidelines for the device industry to follow. Patients deserve nothing less.

The opinions expressed in this article reflect the views of the authors and are not endorsed by Guidant or any of the institutions or organizations with which the authors are affiliated.

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